

End Stage Renal Disease (ESRD) Facilities: CMS Flexibilities to Fight COVID-19

*** Indicates items added or revised in the most recent update*

Since the beginning of the COVID-19 Public Health Emergency, the Trump Administration has issued an unprecedented array of temporary regulatory waivers and new rules to equip the American healthcare system with maximum flexibility to respond to the 2019 Novel Coronavirus (COVID-19) pandemic. These temporary changes will apply immediately across the entire U.S. healthcare system for the duration of the emergency declaration. The goals of these actions are to 1) expand the healthcare system workforce by removing barriers for physicians, nurses, and other clinicians to be readily hired from the community or from other states; 2) ensure that local hospitals and health systems have the capacity to handle a potential surge of COVID-19 patients through temporary expansion sites (also known as CMS Hospital Without Walls); 3) increase access to telehealth in Medicare to ensure patients have access to physicians and other clinicians while keeping patients safe at home; 4) expand in-place testing to allow for more testing at home or in community based settings; and 5) put Patients Over Paperwork to give temporary relief from many paperwork, reporting and audit requirements so providers, health care facilities, Medicare Advantage and Part D plans, and States can focus on providing needed care to Medicare and Medicaid beneficiaries affected by COVID-19.

CMS is providing additional flexibilities under the Medicare program related to training and audits, preventive maintenance, emergency preparedness, patient assessment, care planning, home visits, home dialysis machine designation, Special Purpose Renal Dialysis Facilities (SPRDF) designation, dialysis patient care technician certification, physician credentialing, and payment and reimbursement.

Patients Over Paperwork

- *Training Program and Periodic Audits:* CMS is waiving the requirement at §494.40(d) related to the condition on Water & Dialysate Quality, specifically that on-time periodic audits for operators of the water/dialysate equipment are waived to allow for flexibilities.
- *Equipment Maintenance & Fire Safety Inspections:* CMS is waiving requirements at §494.60(b) and §494.60(d) to reduce non-essential people entering the facility to reduce risk of exposure to the virus. These waivers are intended to ensure that dialysis facilities are able to focus on the operations related to the Public Health Emergency.
- *Emergency Preparedness:* CMS is waiving the requirements at §494.62(d)(iv) which requires ESRD facilities to demonstrate as part of their Emergency Preparedness

Training and Testing Program, that staff can demonstrate that, at a minimum, its patient care staff maintains current CPR certification. CMS is waiving the requirement for maintenance of CPR certification during the COVID-19 emergency due to the limited availability of CPR classes.

- *Ability to Delay Some Patient Assessments:* To ensure that dialysis facility staff can focus on the increased care demands related to the COVID-19 pandemic, CMS is waiving certain requirements at §494.80(b) related to the frequency of assessment for patients admitted to the dialysis facility. CMS is waiving the “on – time” requirements for the initial and follow up comprehensive assessments within the specified timeframes as noted below. This waiver applies to assessments conducted by members of the interdisciplinary team, including: registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. CMS is not waiving subsections (a) or (c) of 42 CFR §494.80. We maintain expectations for conducting the assessment, ensuring the adequacy of the dialysis treatment, and assessing the patient’s needs when there is a change in condition.
Specifically, CMS is waiving:
 - §494.80(b) (1): An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.
 - §494.80(b) (2): A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in §494.90.
- *Home dialysis machine designation - clarification:* The ESRD Conditions for Coverage (CfCs) do not explicitly require that each home dialysis patient have their own designated home dialysis machine. The dialysis facility is required to follow FDA labeling and manufacturer’s directions for use to ensure appropriate operation of the dialysis machine and ancillary equipment. Dialysis machines must be properly cleaned and disinfected to minimize the risk of infection based on the requirements at 42 CFR 494.30 *Condition: Infection Control* if used to treat multiple patients.
- *Accelerated/Advance Payments:* In order to provide additional cash flow to healthcare providers and suppliers impacted by COVID-19, CMS expanded and streamlined the Accelerated and Advance Payments Program, which provided conditional partial payments to providers and suppliers to address disruptions in claims submission and/or claims processing subject to applicable safeguards for fraud, waste and abuse. Under this program, CMS made successful payment of over \$100 billion to healthcare providers and suppliers. As of April 26, 2020, CMS is reevaluating all pending and new applications for the Accelerated Payment Program and has suspended the Advance Payment Program, in light of direct payments made

available through the Department of Health & Human Services' (HHS) Provider Relief Fund. Distributions made through the Provider Relief Fund do not need to be repaid. For providers and suppliers who have received accelerated or advance payments related to the COVID-19 Public Health Emergency, CMS will not pursue recovery of these payments until 120 days after the date of payment issuance. Providers and suppliers with questions regarding the repayment of their accelerated or advance payment(s) should contact their appropriate Medicare Administrative Contractor (MAC).

- *Provider Enrollment:* CMS has established toll-free hotlines for all providers and Part A certified providers and suppliers establishing isolation facilities to enroll and receive temporary Medicare billing privileges. In addition, the following flexibilities are provided for provider enrollment:
 - Waive certain screening requirements.
 - Postpone all revalidation actions.
 - Expedite any pending or new applications from providers.

Medicare appeals in Fee for Service, Medicare Advantage (MA) and Part D

- CMS is allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractor (QICs) in the FFS program 42 CFR 405.942 and 42 CFR 405.962 and MA and Part D plans, as well as the Part C and Part D Independent Review Entity (IREs), 42 CFR 562, 42 CFR 423.562, 42 CFR 422.582 and 42 CFR 423.582 to allow extensions to file an appeal;
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and the Part C and Part D IREs to waive requirements for timeliness for requests for additional information to adjudicate appeals; MA plans may extend the timeframe to adjudicate organization determinations and reconsiderations for medical items and services (but not Part B drugs) by up to 14 calendar days if: the enrollee requests the extension; the extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or, the extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest 42 CFR § 422.568(b)(1)(i), § 422.572(b)(1) and § 422.590(f)(1);
- CMS is allowing MACs and QICs in the FFS program 42 C.F.R 405.910 and MA and Part D plans, as well as the Part C and Part D IREs to process an appeal even with incomplete Appointment of Representation forms 42 CFR § 422.561, 42 CFR § 423.560. However, any communications will only be sent to the beneficiary;
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs to process requests for

appeal that don't meet the required elements using information that is available 42 CFR § 422.562, 42 CFR § 423.562.

- CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs, 42 CFR 422.562, 42 CFR 423.562 to utilize all flexibilities available in the appeal process as if good cause requirements are satisfied.

Cost Reporting

- ****CMS is delaying the filing deadline of certain cost report due dates due to the COVID-19 outbreak.** We are currently authorizing delay for the following fiscal year end (FYE) dates. CMS will delay the filing deadline of FYE 10/31/2019 cost reports due by March 31, 2020 and FYE 11/30/2019 cost reports due by April 30, 2020. The extended cost report due dates for these October and November FYEs will be June 30, 2020. CMS will also delay the filing deadline of the FYE 12/31/2019 cost reports due by May 31, 2020. The revised extended cost report due date for FYE 12/31/2019 will be August 31, 2020. For the FYE 01/31/2020 cost report, the extended due date is August 31, 2020. For the FYE 02/29/2020 cost report, the extended due date is September 30, 2020.

Medicare Telehealth for ESRD

- *Time period for initiation of care planning and monthly physician visits:* CMS is modifying two requirements related to care planning, specifically:
 - §494.90(b)(2): CMS is modifying the requirement which requires the dialysis facility to implement the initial plan of care within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. This modification will also apply to the requirement for monthly or annual updates of the plan of care within 15 days of the completion of the additional patient assessments. CMS is waiving the time requirement for plan of care implementation during the time period of the national emergency.
 - §494.90(b)(4): CMS is modifying the requirement which requires the ESRD dialysis facility to ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, and periodically while the hemodialysis patient is receiving in-facility dialysis. CMS is waiving the requirement for a monthly in-person visit if the patient is considered stable and also recommend exercising telehealth flexibilities, e.g. phone calls, to ensure patient safety.
- *Dialysis home visits to assess adaptation and home dialysis machine designation:* CMS is waiving the requirement at 494.100(c)(1)(i) which requires the periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility

personnel. For more information on existing flexibilities for in-center dialysis patients to receive their dialysis treatments in the home, or long-term care facility, reference QSO-20-19-ESRD.

CMS Facility without Walls (Temporary Expansion Sites)

- *Special Purpose Renal Dialysis Facilities (SPRDF) designation expanded:* CMS authorizes the establishment of SPRDFs to address access to care issues due to COVID-19 and the need to mitigate transmission among this vulnerable population. This will not include the normal determination regarding lack of access to care as this standard has been met during the period of the national emergency. Approval as Special Purpose Renal Dialysis Facility does not require Federal survey prior to providing services.
- *Furnishing dialysis services on the main premises:* ESRD requirements at §494.180(d) require dialysis facilities to provide services directly on its main premises or on other premises that are contiguous with the main premises. CMS is waiving this requirement to allow dialysis facilities to provide service to its patients in the nursing homes, long-term care facilities, assisted living facilities and similar types of facilities, as licensed by the state (if applicable). CMS continues to require that services provided to these patients or residents are under the direction of the same governing body and professional staff as the resident’s usual Medicare-certified dialysis facility. Further, in order to ensure that care is safe, effective and is provided by trained and qualified personnel, CMS requires that the dialysis facility staff: furnish all dialysis care and services; provide all equipment and supplies necessary; maintain equipment and supplies in the off-premises location; and complete all equipment maintenance, cleaning and disinfection using appropriate infection control procedures and manufacturer’s instructions for use.
- *Clarification for billing procedures:* Typically, ESRD beneficiaries are transported from a SNF/NF to an ESRD facility to receive renal dialysis services. In an effort to keep patients in their SNF/NF and decrease their risk of being exposed to COVID-19, ESRD facilities may temporarily furnish renal dialysis services to ESRD beneficiaries in the SNF/NF instead of the offsite ESRD facility. The in-center dialysis center should bill Medicare using Condition Code 71 (Full care unit. Billing for a patient who received staff-assisted dialysis services in a hospital or renal dialysis facility). The in-center dialysis center should also apply condition code DR to claims if all the treatments billed on the claim meet this condition or modifier CR on the line level to identify individual treatments meeting this condition. The ESRD provider would need to have their trained personnel administer the treatment in the SNF/NF. In addition, the provider must follow the CFCs. In particular, under the CFCs is the requirement that to use a dialysis machine, the FDA-approved labeling must be adhered to (§ 494.100) and it must be maintained and operated in accordance with the manufacturer’s recommendations (§ 494.60) and follow infection control requirements at (§ 494.30).

Workforce

- *Dialysis Patient Care Technician certification:* CMS is modifying the requirement at § 494.140(e)(4) for patient care dialysis technicians which requires certification under a State certification program or a national commercially available certification program within 18 months of being hired as a dialysis patient care for newly employed dialysis patient care technicians. We are aware of the challenges that technicians are facing with the limited availability and closures of testing sites during the time of this crisis. CMS will allow patient care technicians to continue working even if they have not achieved certification within 18 months or have not met on time renewals.
- *Transferability of physician credentialing:* CMS is modifying the requirement at §494.180(c)(1) which requires that all medical staff appointments and credentialing are in accordance with State law, including attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists. CMS will allow physicians that are appropriately credentialed at a certified dialysis facility to provide care at designated isolation locations (or separate COVID-19 only facilities designed to mitigate transmission of the virus) without separate credentialing at that facility. This should be implemented so long as it is not inconsistent with a state's emergency preparedness or pandemic plan.

Additional Guidance

- The Interim Final Rules and waivers can be found at: <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>.
- CMS has released guidance to providers related to relaxed reporting requirements for quality reporting programs at <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>.
- CMS has released guidance to describe standards of practice for infection control and prevention of COVID-19 in dialysis facilities. We also described additional flexibilities for dialysis facilities to mitigate transmission and expand home dialysis options. <https://www.cms.gov/files/document/qso-20-19-esrd.pdf>.